

May [], 2019

The Honorable Alex M. Azar II
Secretary, U.S. Department of Health &
Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator, Centers for Medicare and
Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma,

We are writing today to express our concern with the Centers for Medicare and Medicaid Services' (CMS') plan to include non-invasive ventilators in the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive acquisition program. We are concerned that this action may result in access problems for Medicare beneficiaries who depend on home ventilators to breathe.

Under your leadership, Medicare has taken strides to improve access to and the quality of durable medical equipment (DME) in the home. Specifically, the Centers for Medicare and Medicaid Services (CMS) has issued new regulations to overhaul Medicare's competitive bidding program and to enhance the adequacy of Medicare payments in rural areas not subject to bidding. CMS issued a press release in March outlining its plans for implementing the next round of bidding this summer and unveiled plans to include non-invasive ventilators in the next round.

Invasive and non-invasive ventilators are highly specialized and care-intensive devices that allow fragile, medically complex patients to remain in their home while facing the challenges posed by devastating neuromuscular diseases like ALS and terminal respiratory conditions like end-stage COPD. In addition to mechanically facilitating patients' breathing, ventilators are accompanied by varying degrees of respiratory therapy, device training, remote and in-home monitoring, as well as requiring emergency repair and maintenance. All of this support and all essential accessories such as tubing, masks, and filters, as well as the device itself, are currently subject to one flat monthly payment from Medicare as part of the "frequent and substantial servicing" category.

Competitive bidding reduces reimbursement and limits the number of suppliers that can provide the equipment. But given the unique bundled payment for ventilators, combined with the extensive specialized services that accompany them, we believe there are inherent risks and potential unintended consequences in moving these services to the competitive bidding program.

Even brief delays in access to clinical ventilator support can prove dangerous or even fatal and could result in many patients no longer receiving their care at home. Increased emergency room visits, hospitalizations, and institutionalizations could quickly offset any savings from bidding this item—and would certainly reduce quality of life for Medicare beneficiaries. As you know, Medicare rates have implications for other populations, including children on Medicaid and CHIP, active duty military and their families on TRICARE, and veterans served by the VA,

among others. The adequacy of Medicare payment for critical services like home ventilatory care is paramount.

Medicare has never attempted to bid any items within its entire DME category of devices requiring frequent and substantial servicing. Given that ventilators are critically important to people with diseases such as ALS and COPD, we ask that CMS reconsider including ventilators in the competitive bidding program for round 2021. If the agency decides to move forward with the proposal we respectfully request that CMS give due consideration to the potential negative consequences on fragile medical communities, and the bidding and contract process takes into account medical need, care complexity, and beneficiary access to experienced providers in this specialized field. CMS should also provide clinical guidelines to acknowledge the complexity of non-invasive ventilators compared to other durable medical equipment in order to provide a context for the appropriate standard of care.

Sincerely,

Senate letter